Supreme Court, U.S.
FILED
MAR 14 1986
JOSEPH F. SPANIOL, JR.
CLERK

No. 85-664

IN THE
Supreme Court of the United States
OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE,
PUBLIC CITIZEN and LINDA S. BARDOT,
Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE
DISTRICT OF COLUMBIA CIRCUIT

BRIEF OF RESPONDENTS

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QUESTION PRESENTED

May the Food and Drug Administration set the permissible level for an acknowledged carcinogen in food without permitting any public participation, when the Food, Drug, and Cosmetic Act provides that the agency "shall promulgate regulations limiting the quantity" of such a substance through a formal rulemaking proceeding?

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ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF OF RESPONDENTS

This case concerns the method used by the Food and Drug Administration ("FDA") to regulate environmental contaminants called "aflatoxins." Although the FDA admits that aflatoxins are a poisonous substance for which there is no safe level, since 1969 it has officially sanctioned the sale of corn and certain other agricultural products containing aflatoxins. Respondents do not challenge the FDA's authority to permit the sale of foods containing unavoidable substances such as aflatoxins. Instead, the issue in this case concerns the legality of the method chosen by the FDA to set the allowable level of aflatoxins and other unavoidable, poisonous substances that enter the food supply.

This case turns on section 406 of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), 21 U.S.C. § 346, which provides that the FDA "shall" issue regulations limiting the permissible levels of substances such as aflatoxins. Section 701(e), 21 U.S.C. §

371(e), in turn lists section 406 as one of the provisions of the Act that is subject to formal rulemaking requirements. However, rather than use these procedures to regulate these substances, the FDA has created a device which it calls "action levels," under which food containing less than the prescribed amount of the substance may be lawfully sold. Although "action levels" have the same legal effect as a regulation issued under section 701(e), the FDA issues them without providing any opportunity for public participation. Because respondents seek the opportunity to present their own evidence and to comment on the evidence relied on by the FDA in setting the permissible levels of aflatoxins, they brought this action to require the FDA to comply with the clear mandate of section 406.

STATUTES INVOLVED

The Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717 (1938), 34 Stat. 770, 21 U.S.C. §§ 301, *et seq.*, provides in pertinent part as follows:

Adulterated Food

Sec. 402 [21 U.S.C. § 342]. A food shall be deemed to be adulterated—

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or

(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 406. . . .

Tolerances for Poisonous Ingredients in Foods

Sec. 406 [21 U.S.C. § 346]. Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

Regulations and Hearings

Sec. 701(e) [21 U.S.C. § 371(e)]. (1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406, 501(b), or 502(d) or (h) of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested persons, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. . . .

* * * *

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. . . .

STATEMENT

A. Aflatoxins

Aflatoxins are a group of chemically related substances produced by molds that grow on corn and other agricultural products. Sometimes described as "the most potent carcinogen known in laboratory animals,"[1] they have been shown to cause liver tumors in six species of animals, and epidemiological studies conducted in Southeast Asia and Africa indicate that aflatoxins are human carcinogens. J.A. 35-36. While no similar studies have been conducted in the United States, the FDA has consistently treated aflatoxins as "liver carcinogens" with "extreme potency," and on this basis the agency concluded in 1974 that it should "take actions to hold human exposure to aflatoxins in the United States to the lowest level possible." *Id.* The FDA estimated that eliminating aflatoxins in peanuts alone would reduce the lifetime incidence of liver cancers in the United States by 2,200. Merrill & Schewel, *FDA Regulation of Environmental Contaminants of Food*, 66 Va. L. Rev. 1357, 1408 (1980).

Aflatoxin B_1, the most prevalent member of the strain, is many times more potent than most carcinogens regulated by the FDA. For example, when the FDA proposed to ban saccharin, it relied on animal studies which showed that the sweetener caused cancer in approximately 10% of male rats that were fed a diet consisting of up to 5% saccharin. 42 Fed. Reg. 19996, 20000 (1977). By contrast, in an aflatoxins study relied on by the FDA, where the incidence of tumors was approximately 10%, the animal food contained only one part per billion ("ppb") of aflatoxins (J.A.

[1] National Academy of Sciences, *Scientific and Societal Considerations, Food Safety Policy* 3—49 (March 1979).

36); in another study, where rats were fed a diet of 15 ppb of aflatoxins, all 25 animals developed liver tumors. *Id.*

The FDA has endorsed the validity of these animal studies on aflatoxins, and, in a 1974 Federal Register notice, the agency stated that aflatoxins are "among the most potent liver carcinogens known" and that "there is no known acceptable level of intake of aflatoxins." J.A. 35, 46. These studies and the FDA's consistent position that any level of a carcinogen entails a risk to human health demonstrate that there simply is no basis for the FDA's current suggestion (Br. 44 n.44) that food containing aflatoxins is safe as long as it complies with the FDA's action levels.[2] *See also United States v. Boston Farm Center, Inc.*, 590 F.2d 149, 152 (5th Cir. 1979)(FDA expert testified that "there is no known level of exposure [of aflatoxins] which can be considered safe, without risk to people").

B. The Regulation of Aflatoxins

In order to assess the validity of the FDA's use of action levels here, it is necessary to review briefly the relevant statutes and the history of the FDA's regulation of aflatoxins. Section 301(a) of the FDC Act, 21 U.S.C. § 331(a), prohibits the introduction in interstate commerce of any food that is "adulterated." Section 402 of the Act, 21 U.S.C. § 342, contains several definitions of "adulterated" foods, two of which are relevant here. First, under section 402(a)(1), a food is "adulterated" if it contains a "poisonous or deleterious substance which may render it injurious to health." Because the FDA has consistently maintained that there is no known safe level of aflatoxins, foods containing aflatoxins are adulterated under this provision, and thus the FDA may prosecute persons shipping foods containing aflatoxins. Of course, nothing in the statute requires the FDA to initiate

[2] For example, in 1979, when it banned the use of DES as an animal drug, even though the residue in meat was only a few parts per billion, the FDA relied on the opinion of one of its experts that "exposure to any amount of a carcinogen, however small, will contribute to the total carcinogenic effect in the population." 44 Fed. Reg. 54852, 54885 (1979).

enforcement actions against every food that falls within this section, and it may as a matter of prosecutorial discretion choose not to allocate its resources in particular cases after considering such factors as the seriousness of the violation and its competing priorities. *See Heckler v. Chaney*, 105 S. Ct. 1649 (1985).

Second, under section 402(a)(2)(A), a food is also considered to be adulterated "if it bears or contains any added poisonous or deleterious substance . . . which is unsafe within the meaning of section 406." Section 406, 21 U.S.C. § 346, in turn applies to poisonous and deleterious substances that are added to foods. The parties agree that section 406 is applicable to the regulation of aflatoxins because the substance is "added" to foods such as corn by the growth of a mold on the food. However, because aflatoxins are unavoidable in corn, the substance is covered by a specific portion of section 406 which provides that for such substances

> *the Secretary* [of Health and Human Services] *shall promulgate regulations* limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health.

21 U.S.C. § 346 (emphasis supplied).[3] Section 701(e) of the Act provides that these regulations, which are known as "tolerances," shall be issued pursuant to the formal rulemaking requirements of the Act, which include providing interested persons notice, an opportunity to comment, and, if there are any material issues of facts in dispute, an evidentiary hearing. 21 U.S.C. § 371(e). In order to obtain a tolerance, a food producer must demonstrate that the proposed tolerance is the lowest feasible level of the substance and that there will be no threat to the public health. 21 U.S.C. § 346; 21 C.F.R. §§ 109, 509 (1985).

[3] The Secretary has delegated these responsibilities to the Commissioner of the FDA, 21 C.F.R. § 5.10 (1985), and therefore throughout this brief respondents generally refer to the duties under the FDC Act as those of the Commissioner, even though the Act delegates authority only to the Secretary.

Once a tolerance is established, a food which contains a contaminant that exceeds the level of that tolerance is automatically considered "unsafe" within the meaning of section 402(a)(2)(A), and it is thereby prohibited. By the same token, the tolerance operates like a license for food producers, since, as long as the tolerance is in effect, a food containing the contaminant below the level is not unsafe and hence prohibited by section 402(a)(2)(A), nor is it adulterated under the general adulteration standard contained in section 402(a)(1). *See* FDC Act § 406.

The FDA has never issued a tolerance for aflatoxins, but instead the agency limits the public's exposure to them by use of "action levels," a term which does not appear in the FDC Act or the Administrative Procedure Act ("APA"). Action levels are a method of regulation created by the FDA to monitor a variety of substances, including unavoidable contaminants in foods. However, the agency does not issue action levels as regulations, nor does it even publish proposed action levels for comment in the Federal Register. Instead, from time to time it simply announces that it has set new levels.

Despite this significant procedural difference between the issuance of an action level and the adoption of a tolerance, each confers precisely the same benefits on food producers. Thus, provided that the level of a contaminant does not exceed the authorized amount of the action level, food producers receive full protection from FDA enforcement actions. Nevertheless, with one exception, the FDA has not relied on tolerances promulgated under sections 406 and 701(e) to regulate unavoidable poisonous and deleterious substances that are added to foods. 21 C.F.R. §§ 109.30, 509.30 (1985). Instead, it relies almost exclusively on action levels to regulate unavoidable, added substances which it has determined render food adulterated under the FDC Act.

Action levels were initially publicized through press releases or other announcements. J.A. 16. However, in 1974, the FDA proposed regulations that would have governed the use of action levels and tolerances. J.A. 11. As explained in the proposal, the

major difference between the two methods of regulation is that tolerances would have been used "in relatively static circumstances," while action levels would have been used "prior to promulgation of a section 406 tolerance [where the relevant factors to be considered were] rapidly changing." J.A. 21; *see also* J.A. 28-29. In either case, public participation would have been required. However, for action levels, the FDA would have used only the notice and comment procedures in the APA, 5 U.S.C. § 553, whereas it would have issued tolerances in compliance with the formal rulemaking requirements of section 701(e) of the FDC Act. *See* J.A. 27 (action levels to be "established by regulation").

In 1965, the FDA established an action level for aflatoxins at 30 ppb, which was the lowest level of contamination that could be detected under the existing technology. J.A. 37. In 1969, the agency reduced the level to 20 ppb, where it remains 17 years later. When the FDA proposed issuing the action level regulations in 1974, it also proposed a specific tolerance of 15 ppb for aflatoxins in peanuts. J.A. 33. In the Federal Register announcement, the FDA Commissioner explained that he had concluded that continued use of an action level to regulate aflatoxins would only be appropriate "when changes are foreseeable in the near future that might affect the appropriateness of the limitation established." J.A. 47. Because the FDA was "unaware of any new or anticipated developments that would affect the proposed 15 ppb level in the near future," the Commissioner proposed to issue a tolerance for aflatoxins in peanuts. J.A. 47-48. However, the agency never acted on that proposal, and, as a result, aflatoxins in all foods continue to be regulated solely by the 1969 action level of 20 ppb. *See* J.A. 150.

In 1977, the agency issued final regulations regarding its use of action levels and tolerances and published all existing action levels in its Administrative Guidelines Manual. J.A. 53; *see* J.A. 148. In the preamble to the regulations, the FDA responded to a comment that it "must either disclaim any intent to attach the force of law to its action levels, or it must adopt those action levels as tolerances under section 406 of the act and in accord

with the procedures specified in section 701(e) of the act." J.A. 75-76. Not only did the FDA reject this argument, but in its final regulations it deleted the requirement that it comply with the notice and comment procedures of the APA before issuing or amending an action level. J.A. 80. The FDA justified its decision not to comply with the notice and comment requirements of the APA on the ground that action levels would be used only where "industrial practices are improving. . . quickly" or where the data needed to set a tolerance are "scanty" but "are being developed." J.A. 68-70. The FDA stated that in the future it would publish a notice in the Federal Register inviting public comment on new or revised action levels. *See* 21 C.F.R. §§ 109.4(b)(2), 509.4(b)(2) (1985). However, it reserved the right to change its action levels at any time, without allowing the public an opportunity to participate. *Id.* Despite the absence of any procedural protections for the public, action levels have the force of law, as the FDA acknowledged in the Federal Register notice, since food producers are protected so long as the level of contaminants found in food is below the action level. *See also* Pet. App. 1a, 15a (opinion of court of appeals below); J.A. 148 (FDA Action Levels); *United States v. Ewig Brothers Co.*, 502 F.2d 715, 724-25 (7th Cir.), *cert. denied*, 420 U.S. 945 (1974).

The FDA's actual practice with respect to aflatoxins demonstrates how the agency has implemented its regulation providing for public comment. In 1978, the FDA deviated from its long-standing prohibition against "blending" contaminated foods (*see* J.A. 23), by allowing corn with aflatoxins at levels greater than the 20 ppb action level to be blended with less contaminated corn, in order to obtain a mixture within the 20 ppb limit. The decision was contained in a January 31, 1978 letter to a private firm and was not published in the Federal Register until April 4, 1978. J.A. 101, 172; 43 Fed. Reg. 14122. In the fall of 1980, the FDA again permitted blending of corn containing aflatoxins above the action level, and again it waited several months to publish its decision. J.A. 114. And in 1983, while this lawsuit was pending in the district court, the agency once again announced that it had decided to permit blending of corn con-

taminated with high levels of aflatoxin. J.A. 227. Relying on the FDA's regulations, 21 C.F.R. § 109.4(b)(2)(1985), respondents submitted objections to that decision (J.A. 227), but the agency never responded.

C. Proceedings Below

Respondents are two consumer organizations and an individual consumer. Pet. App. 2a. Their complaint, which was filed after the FDA issued its 1980 blending authorization, alleged that the FDA had violated section 406 of the FDC Act by failing to conduct formal rulemaking to set limits for these unavoidable contaminants. J.A. 111. Respondents also contended that, even if section 406 does not require the FDA to use such tolerances, action levels constitute "rules" within the meaning of section 2(c) of the APA, 5 U.S.C. § 551(4), because they are binding on the agency and have a future effect. *Id.* Therefore, respondents argued, at a minimum the FDA is required to publish action levels as proposed rules, provide an opportunity for public comment, and publish the final rule, with a concise statement of its basis and purpose, thirty days before its effective date. 5 U.S.C. §§ 551(5), 553. *See, e.g., Nader v. CAB*, 657 F.2d 453, 456 (D.C. Cir. 1981)("mandatory language, which narrowly circumscribes the Board's discretion to suspend air fares . . . plainly constitutes a substantive rule"); *American Bus Association v. United States*, 627 F.2d 525, 529 (D.C. Cir. 1980)("[i]f it appears that a so-called policy statement is in purpose or likely effect one that narrowly limits administrative discretion, it will be taken for what it is—a binding rule of substantive law" to which the rulemaking provisions of the APA apply). Finally, respondents claimed that the FDA's policy of permitting blending of corn contaminated with aflatoxins violated both the FDC Act and the agency's own regulations. J.A. 111.

The district court rejected all three arguments, but the court of appeals reversed on the ground that, under sections 406 and 701(e) of the FDC Act, the FDA is required to follow formal rulemaking requirements in setting permissible levels of aflatoxins. Pet. App. 1a, 21a. Thus, in a unanimous opinion by Judge Starr, the court held that "the intent of Congress is abundantly clear in requiring the formal issuance of tolerances, rather than permitting agency reliance solely on informal action levels." Pet. App. 6a. In reaching its decision, the court relied principally on the plain language of the statute, concluding that the "presence of the critical word 'shall' plainly suggests a directive to the Secretary to establish a tolerance." *Id.* As further support, the court observed that "[t]he interpretation accorded the Act by the FDA flies in the teeth of Congress' clear intent and, under long established principles of administrative law, must therefore be rejected." *Id.* Contrary to the FDA's characterization (Br. 25, 34), the court of appeals did not discuss the legal status of foods containing added, unavoidable contaminants for which no tolerance has been issued, nor did it hold that such foods are *per se* unsafe under section 402(a)(2)(A). Instead, the court merely held that when the FDA officially sanctions an unavoidable contaminant such as aflatoxins, it is obligated to comply with the rulemaking requirements of sections 406 and 701(e).

Since the court of appeals held that the FDA is required to comply with these provisions of the FDC Act, it did not reach respondents' alternative claim that the FDA had also violated the notice and comment requirements of the APA, and it remanded the blending issue to the district court for consideration in light of its decision. Pet. App. 15a-16a. The agency's petition for rehearing and suggestion for rehearing *en banc* was denied, with a notation that no member of the court had requested a vote on whether the case should be reheard by the full court. Pet. App. 18a, 19a.

SUMMARY OF ARGUMENT

The issue in this case can be resolved by the plain meaning of section 406 of the FDC Act. That section establishes a standard for determining whether foods with added but unavoidable contaminants are adulterated, and thereby unlawful. Since, as the parties agree, aflatoxins are added, unavoidable contaminants, section 406 requires that the FDA "*shall* promulgate regulations

limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health" (emphasis supplied). In addition, section 701(e) of the Act directs the FDA to use formal rulemaking procedures when it sets such tolerances under section 406. Thus, it is difficult to imagine how Congress could have drafted statutory language which more clearly expressed its intent that the FDA set the permissible levels for substances such as aflatoxins through a formal rulemaking proceeding.

Instead of following the statutory scheme crafted by Congress, the FDA uses "action levels" to regulate aflatoxins and, with one exception, all other unavoidable contaminants. Even though the FDA issues action levels without affording the public an opportunity to comment, they have the same legal effect as a tolerance since an action level binds the agency from proceeding against food producers whose products contain contaminants below the action level specified by the FDA. However, because the FDC Act explicitly requires the FDA to use formal rulemaking procedures to set tolerances for substances such as aflatoxins, the FDA cannot use action levels for this purpose.

Under the FDA's construction of section 406, the statute would have precisely the same meaning if Congress had used the phrase "is authorized to" in place of the word "shall." In fact, the legislative history demonstrates that Congress considered and rejected that alternative. The bill adopted by the Senate used the words "is authorized to," but the House Committee changed those words to "shall" in section 406 and made similar changes in four other places in the statute. Therefore, the legislative history demonstrates that Congress consciously chose to require the FDA to issue regulations for substances covered by section 406 instead of simply granting the agency the discretion to do so.

The FDA relies on other provisions of the FDC Act to argue that the word "shall" in section 406 really means "may." However, none of the arguments offered to support this construction of the statute is persuasive. The agency's principal contention is that the decision of the court of appeals makes section

402(a)(1) superfluous with respect to added, unavoidable contaminants, since that section prohibits foods that contain added contaminants that "may be injurious to health," but under the decision below all such substances would automatically be covered under section 406. That argument cannot be sustained. Section 402(a)(1) is not superfluous because it is the only provision in the Act which prohibits unavoidable, added substances for which the agency has not yet issued a tolerance under section 406. For example, in the 1960's, when the FDA became aware that aflatoxins are a hazard to the public health, it was obligated to begin the process of establishing a tolerance under section 406. But in the interim, it could have used the general adulteration standard in section 402(a)(1) to proceed against food producers selling food with unhealthy levels of aflatoxins. Thus, between the time that unavoidable contaminants are discovered, and the effective date of the tolerance which the FDA must set under section 406, section 402(a)(1) serves a vital role in the regulation of adulterated products.

Nor is the FDA correct that under the decision below the entire food supply is adulterated under section 402(a)(2)(A). Section 402(a)(2)(A) provides that food is adulterated if it is "unsafe" within 406, and section 406 in turn declares that any food is unsafe if it contains an unavoidable, added poisonous and deleterious substance in excess of the tolerance level promulgated by the FDA. However, because section 402(a)(2)(A) applies only if an existing tolerance has been exceeded, foods containing these contaminants are not in violation of that section if there is no tolerance in effect.

As further support for its argument that the word "shall" in section 406 means "may," the FDA offers a number of policy arguments. Not only are those claims irrelevant to the issue of statutory construction, but they are overstated and ignore policies that explain why Congress chose to use the mandatory language of section 406. For example, the agency has greatly exaggerated the regulatory burdens which the court of appeals' interpretation of the statute would place on it. As it acknowledges, there are only eight substances which fall within

the ambit of section 406 and which the FDA currently regulates with action levels instead of tolerances. Moreover, the agency's ability to issue summary decisions without granting a hearing and the significant likelihood that hearings would not even be requested for many of the substances suggest that the burden on the agency would be modest. Although the FDA contends that, under respondents' interpretation, it might also be required to issue tolerances for substances which occur in foods in such negligible amounts that they cannot be detected or have not yet been discovered, this contention is based on speculation and ignores a number of judicial precedents which suggest that section 406 may not apply to such substances.

The FDA accurately points out that it would have less flexibility in regulating contaminants through tolerances since, once a tolerance is issued, food producers may sell food with contaminants below the tolerance level without fear of prosecution. However, this scheme, which essentially amounts to giving food producers a license to sell foods with a certain amount of contaminants, is the same scheme that Congress chose for similar substances which are sanctioned by the FDA for use in foods. It is also unlikely that the FDA would ever need to act on an emergency basis to lower a tolerance for an added unavoidable contaminant, since such substances have been identified in the environment for a long time. If there were ever such an emergency, the agency has the ability to revoke a tolerance on an expedited basis.

In any event, the FDA totally ignores the benefits of using section 406 to regulate substances such as aflatoxins. Under its current practice, each time the FDA brings a case based on a violation of an action level, it must prove as a fact that food contaminated with aflatoxins "may be injurious to health." On the other hand, if there were a tolerance for aflatoxins, the only issue in an enforcement proceeding would be whether the level of the contaminant exceeds the tolerance. Moreover, by permitting public participation, the agency would make more informed decisions regarding the regulation of substances which are poisonous or deleterious when added to foods. The important point, however, is that, regardless of the merits of either method, Congress explicitly chose to require the FDA to use tolerances issued under sections 406 and 701(e).

Finally, the Pesticide Amendments of 1954 demonstrate that the FDA should be required to convince Congress of the merits of its position if it desires to change section 406 from "shall" to "may." The FDA successfully made such a case in 1954 with regard to pesticides, and as a result Congress exempted pesticides from section 406 by creating a new, more expeditious procedure for regulating them. The fact that the FDA believed it needed a congressional amendment to section 406 in order to use different procedures to set the allowable levels for pesticides highlights the error of its argument that the procedural requirements in section 406 and 701(e) are merely permissive. Moreover, the fact that Congress left section 406 in place for all other contaminants further demonstrates that Congress intended the FDA to provide an opportunity for public participation under section 701(e) before it establishes the permissible levels of aflatoxins and other unavoidable contaminants.

ARGUMENT

SECTION 406 OF THE FDC ACT REQUIRES THE FDA TO ALLOW PUBLIC PARTICIPATION PRIOR TO AUTHORIZING UNAVOIDABLE CONTAMINANTS THAT ARE ADDED TO FOODS.

A. The Language and Structure of the FDC Act Require the FDA to Comply With Formal Rulemaking Procedures Before Approving Added, Unavoidable Contaminants in Foods.

Section 406 of the FDC Act states that:

> [any] poisonous or deleterious substance added to any food *except where such substance* is required in the production thereof or *cannot be avoided by good manufacturing prac-*

tice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a) [the adulteration provision].

21 U.S.C. § 346 (emphasis supplied). The parties agree that aflatoxins in corn are an added substance which is poisonous or deleterious within the meaning of the Act and that the Act prohibits the sale of corn containing aflatoxins unless the substance falls within one of the exceptions contained in section 406. One exception applies to substances which "cannot be avoided by good manufacturing practice," and the parties also agree that aflatoxins are such a substance. J.A. 148, 150.

If Congress had stopped at the portion of the statute quoted above, then section 406 would not apply to aflatoxins or to other unavoidable substances. In that event, aflatoxins would be regulated only by section 402(a)(1), which deems any food to be "adulterated" if it contains an added substance which "may render it injurious to health." 21 U.S.C. § 342(a)(1). Since there is no known safe level of aflatoxins, the FDA would have a very strong argument that the shipment of food with any detectible level of the substance violates section 402(a)(1) and hence section 301(a). However, given its other responsibilities, the FDA, in the exercise of its discretion, might not proceed when a violation was technical but trivial. *Heckler v. Chaney, supra.*

Relying on section 402(a)(1) alone to set the adulteration standard for foods with unavoidable contaminants would create two problems. First, food processors would be continually at jeopardy since they would have no guarantee as to how the agency intended to exercise its discretion. Second, the FDA would be limited to bringing individual enforcement actions and in each case would have to carry the burden of proving that the level of the contaminant in the food at issue "may render it injurious to health." This approach would require the FDA to use considerable resources and would also create a risk of inconsistent results, which is inherent whenever issues of fact must be established *de novo.* For this reason, at hearings on the original version of the FDC Act, Walter Campbell, Chief of the FDA,

testified that the case-by-case method was inadequate for the regulation of added, unavoidable contaminants. *Foods, Drugs, and Cosmetics: Hearings on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce,* 73d Cong., 2d Sess. 19-21 (1933) (hereinafter *"1933 S. 1944 Hearings"*). The Agency therefore requested that Congress give it the authority to issue tolerances which would have the force of law, which Congress did in sections 402(a)(2)(A) and 406. Section 402(a)(2)(A) states that a food is "adulterated" if "it bears or contains any added poisonous or added deleterious substance. . .which is unsafe within the meaning of section 406." Section 406 in turn provides that if an added "poisonous or deleterious substance" is "required or cannot be. . . avoided,"

> the Secretary *shall* promulgate regulations limiting the quantity therein or thereon *to such extent as he finds necessary for the protection of public health.*

21 U.S.C. § 346 (emphasis supplied).

A tolerance promulgated under section 406 is binding on both food producers and the FDA. Thus, if a food contains a poisonous or deleterious substance in an amount exceeding the tolerance, section 406 declares that it "shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a)." In that event, the FDA need not present evidence on safety in court, but it need only show that the amount of the substance found in foods exceeds the tolerance level set under section 406.

On the other hand, the statutory scheme protects food producers if the level of the added substance is below the tolerance. Thus, since section 406 deems added, unavoidable contaminants "unsafe" only if a tolerance is exceeded, section 402(a)(2)(A) does not apply if the level of the contaminant is below the tolerance level. Likewise, section 406 explicitly states that while a tolerance is in effect, a "food shall not. . . be adulterated within the meaning of clause (1) of section 402(a)," which provides that foods are adulterated if they contain a substance which "may render it injurious to health." Thus, sec-

tion 406 both conserves FDA resources by eliminating the need to litigate in each case whether a substance may be injurious to health, and it protects a food producer from an adulteration charge under either section 402(a)(1) or 402(a)(2)(A), so long as its products comply with the tolerance level.

Relying on the words "shall promulgate regulations," the court of appeals held that section 406 requires the FDA to issue regulations when it decides to approve the sale of foods containing a substance such as aflatoxins. Pet. App. 6a. This interpretation follows directly from the plain meaning of section 406. According to *Webster's Ninth New Collegiate Dictionary* 1081 (1985), the word "shall" is "used in laws. . . to express what is mandatory." An example provided by *Webster's* is "it shall be unlawful to carry firearms." *Id.* Just as one would have to ignore the plain meaning of that legal command to read "may" for "shall," the FDA's argument that the FDC Act only "authorizes," rather than compels, it to promulgate regulations contradicts the plain meaning of section 406. Indeed, perhaps for this reason, the FDA conceded in its petition to this Court that the interpretation of section 406 adopted by the court of appeals is "entirely rational and plausible." Pet. 8.

The principal argument which the FDA advanced below was that the second italicized portion of section 406—"to such extent as he finds necessary for the protection of public health"—modifies the word "shall," and therefore that section 406 merely gives the Secretary the discretion to issue tolerances, rather than compelling him to do so. The flaw in this argument is that it has no support in the language of the statute or in the structure of section 406. As the court of appeals explained, it is "clear from the structure of the sentence at issue here that the phrase relied upon by the Secretary simply does not modify the pivotal word 'shall.'" Pet. App. 7a. If Congress had intended the qualifying language to modify "shall," it would have placed the qualification adjacent to that word. However, Congress placed that phrase where it did because it intended "the qualifying phrase [to serve] an entirely different office; it explains the standard that the Secretary is to employ in setting the tolerance." *Id.*;

see United States v. General Foods Corp., 446 F. Supp. 740, 745 (N.D.N.Y.), *aff'd*, 591 F.2d 1332 (2d Cir. 1978)("Congress has apparently *mandated* that the F.D.A. establish tolerances for poisonous or deleterious substances which are required or unavoidable in the production of food")(emphasis supplied).

Other provisions in the Federal Food, Drug, and Cosmetic Act, which Congress enacted in 1938, also demonstrate that Congress intended the word "shall" to have its customary meaning. Section 406(b) directed that "the Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food. . . ," and section 604 contained an identical provision for cosmetics. FDC Act §§ 406(b), 604, *repealed by* Color Additive Amendments of 1960, 21 U.S.C. § 376. Similarly, in section 501(b) Congress directed that, if the Secretary concludes that tests to measure the purity of a particular drug are not in an official compendium or if those tests are inadequate, "the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium," and if that body fails to prescribe tests within a reasonable time, "the Secretary shall promulgate regulations" prescribing the appropriate tests. Again Congress used the word "shall" to direct the Secretary to undertake certain acts, including the promulgation of regulations through formal rulemaking (*see* section 701(e)), but under the FDA's construction of the statute it could choose never to follow these statutory commands.

Section 401 is illuminating both because it also uses the word "shall" and because, in contrast to section 406, Congress softened its command by giving the Secretary a limited amount of discretion. Thus, section 401 declares that "[w]henever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations. . . establishing for any food a reasonable definition and standard of identity. . . ." As this Court held in *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218, 228 (1942), "[t]he statute *requires* the Administrator to adopt standards of identity which in his judgment 'will' promote honesty

and fair dealing in the interest of consumers" (emphasis supplied). Thus, "[a]cting within his statutory authority he is *required* to establish standards which will guard against the probable future effects of present trends." *Id.* (emphasis supplied). Just as section 401 requires the FDA to adopt regulations establishing standards of identity, which under section 701(e) must also be issued through formal rulemaking, section 406 requires the FDA to promulgate regulations setting tolerances for unavoidable contaminants.

Section 401 also undercuts the FDA's argument that the words "necessary for protection of the public health" in section 406 modify the word "shall." As we have previously pointed out, if Congress had intended to give the FDA discretion to issue tolerances, it would have placed the description of that discretion adjacent to the word "shall." This is precisely the approach it took in section 401, when it began that provision with the qualification "[w]henever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers," which further demonstrates that the standard to be applied in section 406 was not intended to modify the word "shall."

In this Court, the FDA raises two new arguments to support its contention that the structure of the FDC Act supports its interpretation of section 406. Because these contentions were not presented to the panel below, they were not discussed by the court of appeals. The first new argument is that if, as respondents contend, the FDA must issue regulations for all unavoidable poisonous and deleterious substances, then the portion of section 402(a)(1) applicable to added contaminants would be superfluous. Br. 23-25. Relying on the canon of construction that no provision in a statute should be interpreted as being superfluous, the agency contends that section 406 should be interpreted as simply granting it the authority to issue tolerances, rather than directing it to do so.

However, this argument is without merit since, even if section 406 is interpreted as being mandatory, section 402(a)(1) still applies to poisonous and deleterious additives for which the

FDA has not yet issued a tolerance. For example, on the day that the 1938 statute went into effect, the FDA did not have any tolerances in place. Moreover, in subsequent years, more poisonous and deleterious added substances have been identified. But even under respondents' construction of the statute, these substances cannot be regulated under section 406 until the agency has complied with section 701(e). Indeed, this was precisely the status of aflatoxins when their carcinogenicity was discovered in the 1960's, yet the FDA could properly have proceeded against them under section 402(a)(1), pending the promulgation of a tolerance under sections 406 and 701(e). Therefore, since section 402(a)(1) may be used to regulate added contaminants during the interim before a tolerance can be established, it is not superfluous, and thus respondents' construction of the statute would not "jettison" the "case-by-case method of proving adulteration under *Lexington Mill*" (*see* Pet. Br. 30-31). *See United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914).[4]

The FDA resists respondents' argument that one of the uses of section 402(a)(1) is to act as a transitional provision before a tolerance is promulgated, by pointing out that the Color Ad-

[4] Even under the FDA's argument, the case-by-case method of proving adulteration under *Lexington Mill* would survive for inherent contaminants covered by section 402(a)(1). This is because section 402(a)(1) applies to both added and inherent contaminants, whereas section 406 applies only to added substances.

For similar reasons, the lower court decisions cited on page 19 of the FDA's brief have no bearing on the issues raised here. Thus, for example, in *United States v. Boston Farm Center, Inc.*, 590 F.2d 149 (5th Cir. 1979), the court held that the FDA may use its authority under section 402(a)(1) to initiate enforcement proceedings to enjoin the shipment of corn containing aflatoxins in excess of the 20 ppb action level. In the course of its opinion, the Fifth Circuit stated that "the FDA either may adopt formal regulations [under section 406 of the FDC Act], or may litigate the alleged violations on a case-by-case basis." *Id.* at 151. However, that court was not presented with the question of whether section 406 requires the FDA to use formal rulemaking, as opposed to action levels, in establishing permissible levels of unavoidable contaminants such as aflatoxins. Similarly, as the court of appeals indicated (Pet. App. 15a), the same point distinguishes *Flemming v. Florida Citrus Exchange*, 358 U.S. 153 (1958), which was an enforcement action brought for violation of the adulteration provision that prohibited the sale of coal-tar dyes which had not been certified by the FDA.

ditive Amendments, which Congress enacted more than 20 years after it enacted section 406, contain specific transitional provisions. Br. 25; Pub. L. No. 86-618, § 203, 74 Stat. 404-07 (1960). However, in the 1938 Act, Congress did not include transitional provisions similar to those in the Color Additive Amendments. Instead, it used the standards in the 1906 Act to accomplish the transition by incorporating the 1906 standard into the statute (as in the case of section 402(a)(1)), by explicitly exempting products which were subject to the 1906 Food and Drugs Act (as in the case of drugs, 21 U.S.C. § 321(p)(1)), and by delaying the effective date of the 1938 Act (FDC Act § 902(a)). Therefore, the absence of specific transitional provisions in the 1938 Act has no bearing on the question of statutory interpretation presented in this case.

The FDA's second new argument is that, under the decision below, since FDA has not issued any tolerances under section 406, all foods containing unavoidable contaminants (which the FDA argues is virtually the entire food supply) are *per se* adulterated under sections 402(a)(2)(A) and 406. Br. 14, 22-23, 25, 34, 49. To support this argument, the FDA asserts that "under the court of appeals' interpretation, if a tolerance is *not* in effect, a food is 'unsafe' under section 406 and thus adulterated under Section 402(a)(2)(A)." Br. 25 (emphasis in original). The FDC Act does not require this result, nor did the opinion below.

Under section 402(a)(2)(A), a food is adulterated if it contains a "poisonous or deleterious substance" which is "unsafe within the meaning of section 406." Under section 406, such a substance is "unsafe" when it is "added to any food" unless the substance falls into the exception for substances which are "required" or "cannot be avoided." As to unavoidable additives, section 406 directs the FDA to issue formal tolerances, and it declares that "any quantity exceeding the limits *so fixed* shall also be deemed to be unsafe for purposes of [section 402(a)(2)(A)]" (emphasis supplied). Therefore, under the statute, a food is "unsafe" within section 402(a)(2)(A) *only* if it contains an avoidable, added contaminant, or if it contains an unavoidable contaminant at levels in excess of a tolerance that

has been "fixed" by the FDA. While the plain language of section 406 requires the FDA to issue tolerances for substances such as aflatoxins, neither section 406 nor section 402(a)(2)(A) renders unavoidable added contaminants "unsafe" if there is no tolerance in effect. As explained above, pages 20-22, *supra*, those substances may still be regulated by section 402(a)(1), but foods containing them are prohibited only if the FDA can demonstrate that they contain contaminants at levels which "may be injurious to health."[5]

Nor is the FDA correct in the assertion, made throughout its brief, that the court of appeals reached a contrary construction of the statute. The only citation which the FDA gives for its interpretation of the lower court's opinion is the portion of the opinion which appears at Pet. App. 15a (Br. 49). There the court restated its conclusion that:

> the FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated for the purposes of [section 402(a)(1)] or unsafe for purposes of [section 402(a)(2)(A)].

Fairly read, in the context of respondents' claim that the FDA may not use action levels to *approve* unavoidable added contaminants, the court stated only that the agency must use section 406 when it decides to grant an exemption from the adulteration provisions in section 402(a)(1). It further held that section 402(a)(2)(A) does not apply unless the FDA has promulgated a tolerance. Thus, neither the overall statutory scheme, nor the lower court's opinion, supports the FDA's argument that interpreting section 406 to require the agency to issue tolerances

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[5] Although the court of appeals did not reach this issue, respondents have at times suggested a broader construction of section 406, under which foods would be *per se* "unsafe" if the FDA had not issued a tolerance under section 406. However, respondents do not advocate such a construction here since, under the plain meaning of the statute, section 406 does not cause substances to be "unsafe" simply because no tolerance has been issued.

leads to the conclusion that in the interim all foods that contain substances covered by section 406 are adulterated.[6]

In addition to these new arguments, the FDA adheres to its position that its construction is entitled to substantial deference because it is the expert agency charged with enforcing the FDC Act. However, until relatively recently, the agency never offered an opinion on whether it is required to promulgate tolerances under section 406. The early interpretations quoted in the agency's brief (Br. 17-18 & n.14), its quotations from *Flemming v. Florida Citrus Exchange, supra* (Br. 18), and the quotations from the legislative history (*see* pp. 29-30, *infra*) only acknowledge that the FDA has the authority to issue tolerances under section 406, without resolving the issue of whether it is required to do so.

Even if the FDA had consistently construed section 406 as it does in this action, no deference should be given to the agency's interpretation because the "intent of Congress is clear [and] the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron v. Natural Resources Defense Council*, 104 S. Ct. 2778, 2781-82 (1984); *see also Chemical Manufacturers Association v. Natural Resources Defense Council*, 105 S. Ct. 1102 (1985). Here, by "employing the traditional rules of statutory construction," the Court can ascertain "that Congress had an intention on the precise question at issue," and therefore "that intention is the law and must be given effect." *Chevron v. Natural Resources Defense Council, supra*, 104 S. Ct. at 2782 n.9. Thus, the agency's interpretation of section 406 cannot be upheld because it undercuts the plain meaning of the statute.

There are several other factors which suggest that the FDA's construction here should be accorded less deference than is often the case. First, the FDA's construction eases the regulation of harmful substances in foods. As this Court held in *United States*

[6] There is no inconsistency between respondents' construction of the statute and this Court's decision in *Flemming v. Florida Citrus Exchange*, 358 U.S. 153 (1958). *See* Pet. Br. 22. As petitioner points out, this Court stated in *Flemming* that "[t]he existence of a tolerance is specifically stated in § 406(a) [currently § 406] only to give sanction to what would otherwise amount to adulteration within the terms of § 402(a)(1)." 358 U.S. at 166. Respondents agree.

v. An Article of Drug, 394 U.S. 784, 798 (1969), "we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health." Thus, consistent with this purpose, the Court should construe section 406 to require the FDA to use formal rulemaking, rather than action levels, to authorize added poisonous and deleterious substances in foods.

Second, the deference given to administrative agencies is based, at least in part, on the expertise which those agencies bring to questions of administrative law. However, where the question of statutory interpretation does not depend on a complex, scientific question, the justification for deference is diminished, and accordingly the Court should be less willing to defer to the agency. *See, e.g., Barlow v. Collins*, 397 U.S. 159, 166 (1970). Third, the deference accorded an agency should be tempered where the agency's construction would lessen the burdens which a statute would otherwise place upon it. Here the FDA advocates a construction of the Act which would relieve it of any obligation to engage in public proceedings regarding substances covered by section 406. Since it is in the FDA's self-interest to advocate this construction, the Court should accord it less deference than it would in the ordinary case.

* * *

The irony of the FDA's position on statutory construction is that the principal rationale that it offers for its interpretation of the FDC Act is that the statute must be construed to avoid making section 402(a)(1) superfluous for added contaminants, and yet the result it champions would enable the agency to continue to avoid using section 406 altogether. The irony of this position is further underscored by the agency's reference to the 1933 testimony of FDA Chief Walter Campbell that the tolerance provision in section 406 was "one of the more important provisions of [the] bill" (Br. 28), and yet the FDA has used that provision only twice in 48 years. 9 Fed. Reg. 11836 (1944)(the pesticide flourine spray residues); 21 C.F.R. §§ 109.30, 509.30

(1985)(polychlorinated biphenyls ("PCBs")). At bottom, what the agency's arguments ignore is that Congress provided a very specific method for approving levels of added, unavoidable contaminants: tolerances promulgated under section 701(e). Therefore, by stating that the FDA "shall promulgate regulations" setting limits for these substances, Congress could not have been clearer in its intention that the FDA use only the procedures in sections 406 and 701(e) to approve substances such as aflatoxins.

B. The Legislative History of the 1938 FDC Act Is Consistent With the Plain Meaning of Section 406.

Since the plain language of sections 406 and 701(e) requires the FDA to establish permissible levels of poisonous and deleterious substances that are added to foods only through the issuance of tolerances, this Court need not go beyond the words of the statute to determine that the court of appeals was correct. *Caminetti v. United States*, 242 U.S. 470, 485 (1917)("Where the language is plain and admits of no more than one meaning, the duty of interpretation does not arise, and the rules which are to aid doubtful meanings need no discussion.")

In any event, the legislative history confirms that Congress intended to direct the agency to establish tolerances for unavoidable contaminants only through the formal rulemaking process. Indeed, the legislative history shows that Congress chose language requiring the FDA to set section 406 tolerances for unavoidable, added contaminants after specifically rejecting statutory language which would have merely authorized it to do so. In order to understand precisely how Congress changed the federal laws applicable to adulterated foods in 1938, it is necessary to review briefly the 1906 Act and how the FDA regulated poisonous substances prior to 1938.

Under the 1906 Federal Food and Drugs Act, the FDA's approach to regulating adulterated foods was strikingly similar to the approach that it uses today. Thus, the statute declared a food to be adulterated "[i]f it contain[ed] any added poisonous or other added deleterious ingredient which may render such article injurious to health." 1906 Federal Food and Drugs Act § 7 34 Stat. 770, *repealed by* FDC Act § 902(a). This standard was later incorporated into section 402(a)(1) of the 1938 FDC Act.

Prior to 1938, the FDA had adopted "administrative tolerances" for poisonous and deleterious substances. *1933 S. 1944 Hearings* 22. Those tolerances, like the FDA's current action levels, were issued without notice to the public or an opportunity to comment. While there is no conclusive evidence on this point, the term suggests that, like action levels, administrative tolerances also amounted to a license to market foods as long as the contaminants were below the tolerance level.

Congress adopted the 1938 FDC Act after five years of hearings and debates. As the FDA indicates (Br. 29), the original version of the Act used the word "shall" to describe the agency's obligation to promulgate regulations. S. 1944, 73d Cong., 1st Sess. § 11(a) (1933). Thus, as FDA Chief Campbell testified, under the tolerance provision, "tolerances must be established for fruits and vegetables." *1933 S. 1944 Hearings* 118. The most important aspect of this provision was that for the first time it "authorized" the FDA to issue binding regulations, and perhaps it was for this reason that agency officials used the word "authority" to describe the new power which section 406 would confer upon the agency. *See* Pet. Br. 28. In addition, most of the bills introduced between 1933 and 1937 used the words "is authorized to" in describing the FDA's obligation to issue tolerances for added contaminants. *See* Pet. Br. 30 nn.29, 30. Thus, many of the witnesses who testified at hearings held between 1933 and 1937, and who stated that the bills "authorized" the FDA to adopt tolerances, were accurately describing bills under consideration at the time of their testimony. Pet. Br. 29-31 & nn.24, 28.

The bill which Congress enacted as the FDC Act of 1938 was introduced in the Senate in January 1937. S. 5, 75th Cong., 1st Sess., 81 Cong. Rec. 65 (1937). Section 15(a) was similar to section 406 as enacted in that it declared added, poisonous substances to be "unsafe" unless the substance is required or cannot be avoided. For substances falling within the exception,

however, section 15(a) provided that "the Secretary *is authorized to promulgate* regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health" (emphasis supplied). Section 24(e) of the bill would have afforded the public substantially the same notice and hearing rights as provided by section 701(e) of the FDC Act. With minor changes not relevant here, the "is authorized to" language was approved by the Senate. 81 Cong. Rec. 2019 (1937).

If Congress had adopted the Senate bill, respondents would have no claim under section 406. However, the House Committee on Interstate and Foreign Commerce made a number of changes before the measure was adopted by the House. One of those changes substituted the word "shall" for the words "is authorized to" in section 406(a). House Committee on Interstate and Foreign Commerce, 75th Cong., 1st Sess., S. 5 § 406(a) (Confidential Comm. Print No. 2, 1937), *reprinted in A Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments*, Vol. V at 767, 792 (U.S. Dep't of Health, Education, and Welfare) (hereinafter "*FDC Act Legislative History*"). In addition, the House Committee changed the words "is authorized to" to "shall" in four other places in that Committee Print. *Id.* §§ 401, 406(b), 501(b) & 604. *See also* discussion at pp. 19-20, *supra.*

Neither the House Report, nor the Conference Report, nor any of the statements subsequently made in the Congressional Record directly discusses the reasons for these changes. All that is known is that, in each case, where the Senate bill had used the words "is authorized to," the change to "shall" adopted by the House became law. FDC Act §§ 401, 406(b), 501(b) & 604; *see* 21 U.S.C. §§ 341, 351 (Sections 406(b) and 604 were repealed by the Color Additives Amendments of 1960, 21 U.S.C. § 376.). The fact that the House made these changes in the legislation should be given considerable weight in identifying Congress's intent, since it shows a conscious decision by Congress to use the mandatory word "shall." *See, e.g., Gulf Oil Corp. v. Copp*

Paving Co., 419 U.S. 186, 200 (1974) (change made by Conference Committee "strongly militates against a judgment that Congress intended a result that it expressly declined to enact"); *Pan American World Airways, Inc. v. CAB*, 380 F.2d 770, 781 (2d Cir. 1967) ("[t]hat Congress adopted the House version of the bill, specifically rejecting the Senate's conflicting version, is of course an extremely significant factor in determining what was Congress' intention").

Despite this legislative history, the FDA relies on the following general language from the House Report to support its argument that the House Committee's change from "is authorized to" to "shall" was not intended to require the FDA to issue tolerances under section 406:

> This subsection first prohibits the unnecessary addition of poisons. Where such additions are necessary, the establishment of tolerances is authorized, based upon the practical necessities for the use of poisonous substances.

H.R. Rep. No. 2139, 75th Cong., 3d Sess. 6 (1938). The FDA also relies on similar statements made during the floor debates on the House bill. Br. 33 & n.35. There are several reasons, however, why those general statements are of no help to the FDA on the issue before this Court.

First, the statements are consistent with respondents' interpretation and the literal language of the statute. Thus, the significant aspect of the tolerance-setting provision was that Congress for the first time conferred authority on the FDA to issue regulations which would establish the permissible limits for unavoidable contaminants. Therefore, the principal focus of attention by everyone, including the FDA, was in creating this new authority, not in the procedures that would be utilized in carrying it out. In any event, the fact that the House Committee Report only described the new statute as "authority" given to the agency is consistent with this legislative history and does not undercut the plain language of the statute, which directs the

FDA to use that authority when granting permission to sell foods with unavoidable contaminants in them.[7]

The FDA's argument is further undercut by the four other provisions where the House Committee changed the words "is authorized to" to "shall." *See* pp. 19-20, *supra*. In each case Congress enacted that change into law, but in each case the House Committee Report described the provision as "authorizing" the agency to exercise some new authority. Undoubtedly, for each of these provisions, one could conduct an exercise similar to the one conducted by the agency here and find numerous instances in the legislative history, as well as statements by commentators on the statute, where the statutory provision was described in terms of the "authority" it conferred on the agency. However, the fact that section 406 and these other four provisions in the FDC Act were less than fully described by those seeking to give them a shorthand characterization in the House Committee Report cannot be a sufficient justification for changing the word "shall" into the permissive language that the FDA advocates. Yet this is precisely the argument which the FDA advances in urging the Court to interpret section 406 as though it were never amended by the House to direct the agency to issue regulations for unavoidable contaminants that are added to foods.

In summary, the FDA's interpretation of the legislative history here amounts to a contention that this Court should ignore the word "shall" in section 406 because there is no discussion in the hearings or committee reports which specifically confirms the clear mandatory language in the Act. However, the fact that Congress considered two versions of section 406, and ultimately amended that section to make it mandatory, is far more significant than the absence of a discussion of this aspect of section 406 in the legislative history. Thus,

[7] It is also relevant that the phrase "to such extent as he finds necessary for the protection of public health" was included in the version of S. 5 adopted by the Senate. S. 5, 75th Cong., 1st Sess. § 15(a) (March 10, 1937), *reprinted in FDC Act Legislative History*, Vol. V at 633, 655. The fact that S. 5 used the word "authorized" to describe the authority conferred on the Secretary demonstrates that the phrase was included to describe the standard for setting tolerances, rather than to qualify the word "shall," as the FDA argues. Br. 17.

because the FDA's interpretation of section 406 amounts to a rewriting of the statute and is contrary to the clear, overall Congressional intent, it should be rejected.

C. The FDA's Policy Arguments Are Not A Basis for Overriding the Plain Meaning of Section 406.

In an effort to convince this Court to disregard the language of the statute, the FDA relies on a number of policy considerations. First, the FDA contends that section 406 could also apply to a "whole universe" of substances which occur in only "negligible amounts," many of which are "undetectable using currently-available analytical methods" and others which "may yet be undiscovered." Br. 47 n.49. Not only has the FDA neglected to identify any such substance, but even assuming there were such substances, they would not necessarily be covered by section 406. Thus, if such a substance appeared in minuscule amounts, which could not have been detected in 1938, it arguably may not be "poisonous or deleterious" within the meaning of section 406. Other courts have reached similar conclusions in analogous cases under the FDC Act where new detection methods could literally prohibit foods containing negligible amounts of contaminants that pose no threat to the public health.

For example, in interpreting section 402(a)(3), 21 U.S.C. § 342(a)(3), which prohibits "filthy, putrid, or decomposed substance[s]" in food, the Fifth Circuit has recognized that that section "sets a standard that if strictly enforced, would ban all processed food from interstate commerce" because a "scientist with a microscope" could find such a substance "in almost any canned food we eat." *United States v. 484 Bags, More or Less*, 423 F.2d 839, 841 (5th Cir. 1970), *quoting United States v. 1500 Cases, Etc.*, 236 F.2d 208, 210-11 (7th Cir. 1956). Nevertheless, "the majority, in fact almost unanimous, rule is that the Act confers the power to exclude from commerce all food products which contain in any degree filthy, putrid or decomposed substances," although such "harsh consequences...are tempered by discretion given the Secretary." 423 F.2d at 839 (citations omitted).

Any "harsh consequences" of the court of appeals' decision in this case could also be tempered in the same manner. *See also Developments in the Law—The Federal Food, Drug, and Cosmetic Act,* 67 Harv. L. Rev. 632, 644-45 (1954) (If section 402(a)(3) "were interpreted literally, almost every food manufacturer in the country could be prosecuted," and therefore, "recognizing that some contamination may be inevitable and *de minimis,*" courts have held that section 402(a)(3) does not apply to "a negligible amount of filth or decomposition unavoidable even with the highest care."); *Monsanto v. Kennedy*, 613 F.2d 947 (D.C. Cir. 1979) (negligible amount of substance may be *de minimis* and not a food additive subject to FDC Act §§ 201(s), 409, 21 U.S.C. §§ 321(s), 348); *Scott v. FDA*, 728 F.2d 322, 325 (6th Cir. 1984)(negligible amount of a contaminant in a color additive not subject to anti-cancer clause, FDC Act § 706(b)(5)(B), 21 U.S.C. § 376(b)(5)(B)). Thus, if faced with a similar issue in the context of section 406, a court might reach an analogous result.

In any event, the Court need not rule on the status of these unidentified substances. Instead, this case presents the question of whether the FDA may use action levels to grant what amounts to a license to market foods containing added substances that are known carcinogens, without any public participation, in the face of the plain language of section 406 and the formal rulemaking requirements in section 701(e). Thus, if there are certain unavoidable, added contaminants for which the agency does not even have action levels, the legality of the agency's method of regulating them is simply not at issue here.

Second, the FDA argues that its approach is preferable because formal tolerances might impair its ability to react in the event of an emergency. Br. 44-45. However, the agency has not pointed to a single example of when it has lowered an action level because an emergency has arisen, and respondents are aware of none. Thus, the most likely reason that Congress did not include an emergency provision in section 406, similar to the "imminent hazard" provision applicable to drugs (21 U.S.C. § 355(e)), is that it was not concerned about an emergency arising with respect to known contaminants, which have been in the

environment for a long period of time, and which typically occur in small quantities. In fact, other than the provision applicable to new drugs, Congress did not include emergency authority in any other portion of the 1938 FDC Act. Even subsequent amendments establishing licensing schemes for food and color additives do not give the FDA the authority to act quickly to remove those substances from the market after they have been approved. 21 U.S.C. §§ 348, 376. In any event, if there were truly an emergency, the FDA could act on an expedited basis to modify its tolerance under section 701(e). *See Pennsylvania Gas & Water Co. v. FPC*, 427 F.2d 568, 576 (D.C. Cir. 1970)(agencies have latitude to expedite hearings in the public interest). Therefore, the theoretical argument that the FDA might sometime in the future wish to use emergency authority provides no support for the agency's rewriting of section 406.[8]

Third, the FDA argues that the court of appeals construction places an undue administrative burden on it. Br. 45-48. However, the FDA takes the position that it has issued action levels under section 406 for only eight contaminants, which in turn are present in 21 foods.[9] More importantly, in many respects, the procedures required by sections 406 and 701(e) are

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[8] The FDA's current regulations provide that it will use action levels only in "dynamic circumstances," *i.e.*, when it is impracticable to set tolerances (Br. 7). Even this use of action levels is limited to situations where "technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance." 21 C.F.R. §§ 109.6(c), 509.6(c)(1985). *See also* 42 Fed. Reg. 53814, 53817 (1977)(J.A. 68) ("[A]n action level is appropriate if industrial practices are improving so quickly that the extent to which a substance is avoidable changes significantly from year to year, or if toxicological data are scanty or conflicting but additional data are being developed.") However, aflatoxins plainly do not meet these criteria. More than 10 years ago when it proposed to issue a tolerance for aflatoxins in peanuts, the FDA explained that action levels are "appropriate when changes are foreseeable in the near future that might affect the appropriateness of the limitation established," but that this "is not the case with aflatoxin." J.A. 47. The fact that the agency has not changed the action level for aflatoxins since 1969, and the fact that, with the single exception of PCBs in packaging materials, the FDA regulates all unavoidable contaminants with action levels, also demonstrate that the FDA has not even followed its own regulations concerning the use of tolerances and action levels.

[9] In addition, there are 15 substances for which the FDA has set action levels (J.A. 148), but which the agency apparently contends are subject to section 408 of the FDC Act, 21 U.S.C. § 346a. *Compare* Pet. Br. 47 n.48 *with* 21 U.S.C. § 346a.

not very different from the notice and comment procedures required by the informal rulemaking requirements of the APA. The only significant difference is that section 701(e) requires the agency to hold a hearing before an administrative law judge where there are disputed issues of material fact.

However, it is far from certain that anyone will even request a hearing on any of these substances, or that the FDA would be obliged to hold one. For example, other provisions of the FDC Act require a hearing on decisions pertaining to prescription drugs, food additives, and a variety of other products regulated by the agency. 21 U.S.C. §§ 348(f), 355(e), 376(d). *See* Merrill, *Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act*, 77 Mich. L. Rev. 171, 208 (1978) ("[t]he statutorily prescribed process for approving or withdrawing approval of a food additive is as complex as that required for the establishment of tolerances under section 406"). Even though thousands of products fall within these provisions, the hearing requirement has not paralyzed the FDA because, in most cases, the agency denies the application for a hearing and issues a summary decision, a procedure which this Court upheld in *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620-22 (1973). For example, although the agency has withdrawn 1,116 new drug applications since 1962, it has held only 13 evidentiary hearings concerning such decisions.[10] Therefore, there simply is no basis for assuming that if the FDA were to follow the plain language of section 406, it would be required to hold hearings for even the eight added substances for which it currently has action levels.[11]

[10] These figures were supplied to respondents by counsel for the Food and Drug Administration.

[11] The agency also argues that the burden of issuing formal regulations is demonstrated by the fact that it took the FDA seven years to issue the tolerance for PCBs. However, the FDA has been repeatedly criticized by the courts for its delays in reaching decisions. *See, e.g., Contact Lens Manufacturers Association v. FDA*, 766 F.2d 592, 603 (D.C. Cir. 1985); *General Medical Co. v. FDA*, 770 F.2d 214, 216 (D.C. Cir. 1985); *American Public Health Association v. Veneman*, 349 F. Supp. 1311, 1317 (D.D.C. 1972). Therefore, the amount of time taken to issue a single tolerance is not indicative of how long the agency should reasonably require to comply with sections 406 and 701(e).

In any event, in making this policy argument, the FDA totally ignores the benefits of issuing regulations. Under its current practice, the FDA must prove that corn contaminated with aflatoxins above 20 ppb is adulterated, each time that it brings an action for violation of the action level. *See, e.g., United States v. Boston Farm Center, Inc., supra*. On the other hand, if there were a formal tolerance in effect, the FDA would only have to show that the level of aflatoxins exceeded the tolerance, and any challenge to the tolerance would have to be made directly rather than as a defense to a court action. Thus, while the agency obviously uses resources to set the tolerance, it would save resources in the long run when prosecuting companies for violating the regulation. Also, by permitting public participation, the agency could make more informed decisions regarding the regulation of known carcinogens like aflatoxins.

The Court need not, and should not, resolve the debate between the parties about which public policies are most important. Instead, it is sufficient that Congress could rationally have chosen to require the FDA to issue tolerances for contaminants, and therefore the agency's policy arguments should not be relied upon to avoid the plain meaning of the statute.

D. The Legislative History of the 1954 Pesticide Amendments Supports the Plain Meaning of Section 406.

Unable to sustain its position on the basis of the language of section 406, the FDA has resorted to the argument that, through subsequent action, Congress has sanctioned FDA's use of action levels in regulating added contaminants. On this basis, the FDA argues that its construction of the statute is entitled to "enhanced deference." Br. 39. For this proposition, it relies principally on the legislative history of the 1954 Pesticide Amendments to the FDC Act. FDC Act § 408, 21 U.S.C. § 346a. However, rather than support the FDA's position, the legislative history of these Amendments supports respondents' position. That history demonstrates that the FDA concluded that a statutory amendment was required to permit the agency to deviate from the rulemaking requirements specified in section 406. Moreover,

the history of the 1954 Pesticides Amendment further demonstrates that if there were strong policy reasons for not abiding by a statutorily prescribed regulatory scheme, the appropriate forum for addressing those concerns would be Congress, not the courts.

Prior to the 1954 Pesticide Amendments, pesticides were subject to section 406 of the 1938 Act. Thus, pesticides were poisonous or deleterious substances that were added to foods, but which were "required" within the meaning of that section, since pesticides are needed so that agricultural products can survive the ravage of insects. *See, e.g.*, H.R. Rep. No. 1385, 83d Cong., 2d Sess. 2-3 (1954). Although the FDA had in 1944 issued one formal tolerance for a pesticide under section 406 (Pet. Br. 46 n.46), its resources had been diverted to World War II in the mid-1940's. For that and other reasons, the FDA did not begin to set formal tolerances for pesticides on a wholesale basis until the mid-1950's. *See* Testimony of Charles W. Crawford, FDA Commissioner, *Federal Food, Drug, and Cosmetic Act: Hearing on H.R. 4277 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 83d Cong., 1st Sess. 121 (1953)(hereinafter "*1953 Pesticide Hearing*"). However, by that time, largely due to advances made in the chemical industry as a result of the war, there were hundreds of new pesticides that agricultural producers wanted to use on their products, but for which there were no FDA-sanctioned tolerances. *Id.*

In 1950, the FDA began a rulemaking proceeding pursuant to section 406 that would have set tolerances for approximately 100 different pesticides. *1953 Pesticide Hearing* 121. However, due to the number of substances and parties involved, the volume of data compiled, and the vast agency resources required, none of the tolerances had been issued by 1953. As a result, food producers were uncertain of how much of these substances they could use on their crops without violating the law, and the public was afraid to eat products that had been sprayed with these toxic substances. 100 Cong. Rec. 153 (1954)(remarks of Rep. Miller); H.R. Rep. No. 1385, *supra*, pp.

4-5. Thus, the industry, with the support of the FDA, requested that Congress amend the FDC Act to provide for a less time-consuming and less cumbersome procedure for setting tolerances for pesticides. Congress responded by passing the 1954 Pesticide Amendments, which take pesticides out of the rulemaking requirements of section 406, and instead direct the Secretary to set tolerances for pesticides under a different, more expeditious procedure. *See* FDC Act § 408, 21 U.S.C. § 346a.

This history of the Pesticide Amendments is instructive for a number of reasons. First, if, as the FDA contends, the agency may use action levels without complying with the rulemaking requirements of section 701(e), then in the early 1950's there would have been no reason for the FDA or the industry to seek relief from those requirements in their efforts to expedite the issuance of tolerances for pesticides. Thus, contrary to the FDA's suggestion that Congress knew of its use of informal tolerances and "did nothing to require its abandonment in favor of exclusive reliance on formal rulemaking" (Br. 42), Congress dealt with the problem by enacting a special statutory scheme for establishing tolerances for pesticides.

Second, the argument that Congress intended to sanction the FDA's use of action levels is further undercut by the fact that Congress specifically provided for a means of setting a "temporary tolerance" for pesticides that were being used experimentally. While it is true that Congress may have been aware that the FDA had used informal tolerances to regulate pesticides and other substances covered by section 406 (*see* Pet. Br. 40 n.41), it also recognized that "[t]here are no provisions for such exemptions or temporary tolerances in the present law." H.R. Rep. No. 1385, *supra*, p. 6. Therefore, Congress deemed it necessary to include section 408(j) to give the FDA explicit authority to issue temporary tolerances for experimental pesticides. Under that section, the Secretary may "establish a temporary tolerance for the pesticide chemical. . . whenever in his judgment such action is deemed necessary to protect the public health. . ." 21 U.S.C. § 346a(j). Surely, if the FDA already had a system for bypassing the formal rulemaking re-

quirements of section 406 which was consistent with the FDC Act, there would have been no need for Congress to amend the statute to include section 408.

Third, Congress responded to the specific problems raised with respect to pesticides (*i.e.*, the unanticipated increase in the number of new substances and the need to expedite the procedures for setting tolerances for them), by carving out a separate procedure for regulating pesticides, and not by changing the general scheme for regulating added contaminants under section 406. Thus, the FDA's suggestion (Br. 42) that Congress was generally critical of the formal rulemaking requirements of section 406 is belied by the fact that Congress left that section intact with respect to regulating all added contaminants other than pesticides.[12]

Finally, the history of the 1954 Pesticide Amendments demonstrates that if, as the FDA contends, there are similar policy arguments which would support excluding other contaminants from the formal rulemaking requirements of section 406, those arguments should be made to Congress. If Congress agrees, it can follow the example of the Pesticide Amendments and decide that the regulatory scheme in section 406 is no longer the best way to protect the public from unsafe contaminants in food. But until such time, the FDA must comply with the clear mandate of the FDC Act and allow public participation when establishing the allowable levels of substances such as aflatoxins.

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[12] That Congress intended the requirements of section 406 to continue to apply to all added substances, except pesticides, is demonstrated by the following exchange between Congressman O'Hara and a representative of the National Canners Association:

> *Congressman O'Hara:* This has nothing to do with—this proposed legislation has nothing in the way of an effect upon section 406 of the present law. This is true, is it not?
>
> *Mr. Austern* [on behalf of the National Canners Association]: That is true.

Federal Food, Drug, and Cosmetic Act: Hearing on H.R. 7125 Before the House Comm. on Interstate and Foreign Commerce, 83d Cong., 2d Sess. 32 (1954).

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed. If the Court reverses the judgment below, it should remand the case for a decision on whether the Administrative Procedure Act, 5 U.S.C. § 553, requires the FDA to provide an opportunity for notice and comment on its action levels.

Respectfully submitted,

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March 1986